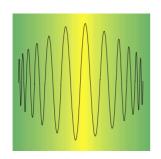


# **High Tone Power Therapy Device**





HiToP® 191

User Manual

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gbo Medizintechnik AG Kleiststrasse 6

#### DE 64668 Rimbach

Telefon: 06 25 3/808-0 Telefax: 06 25 3/808-245 E-Mail: info@gbo-med.de

Internet: http://www.gbo-med.de

Version 2.2

Date of issue November 30th<sup>th</sup>, 2011

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# Warnings and safety precautions



Warning! Warnings which have to be observed by all means!



**Caution!**Observe the instructions for use!



### Note!

Information that will facilitate your work.

#### 1 Introduction

#### 1.1 Intended Use

Electrotherapy with sinusoidal alternating currents.

#### 1.2 Description of the unit

The **HiToP**<sup>®</sup> **191** is a microprocessor-controlled HighTone Therapy device for electrotherapy. Its application range predestines this device for the use at home, in modern and well-equipped hospitals or medical practices.

Thus, the HiToP® (HighTone Power) 191 is well suited for:

- Symptomatic treatment with polyneuropatic aliments like i. E.
  - pain
  - burning
  - prickling
  - numbness
- muscle stimulation

Through external muscle stimulation the metabolism is activated which again results in an improvement of the sensibility to insulin.

Also patients with varicose veins, metal implants, endoprothesis and open wounds (ulcus cruris) may be treated.

Since the electrodes are placed at this Polyneuropathy- treatment exclusively on the legs, also patients with cardiac pacemakers may be treated.

The **HighTone** Power Therapy device **HiToP**® provides a therapy with middle frequency sine waves. The therapy is absolutely free of d.c. components. The frequency range used comprehends 3 octaves, the range of 4096 – 32768 Hz. The therapy frequency is scanned with a defined frequency. This method is called **SimulFAM**® for **Simul**tanous **F**requency **A**mplitude **M**odulation.

#### 1.3 What is High Tone Power Therapy?

High Tone Power Therapy is a specific new development based on scientific knowledge from a number of different disciplines, i. e. it is an inter-disciplinary new development. The specialist knowledge involved is derived from medicine, physics, mathematics, physiology, histology, cytology, chemistry, biochemistry and involves their sub-disciplines.

#### Put briefly and simply:

High Tone Therapy takes the fact that electrical changes in the tissue are always associated with biochemical changes, and vice versa, and puts it to use for therapeutic purposes. In doing so it provides an alternative to medicinal, physical and operative therapies that have so far proven unsatisfactory, risky, associated with side-effects or even unsuccessful, and planned surgical treatment.

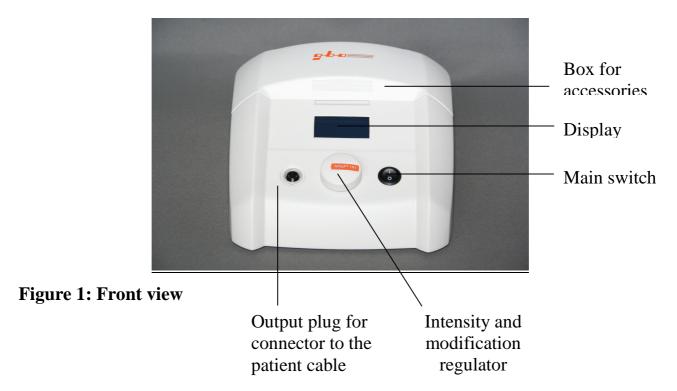
# 1.4 Operating the HiToP® unit

You purchased a HiToP<sup>®</sup> 191. The unit is dedicated for private use.

If you use the unit commercially, it is subjected to the Medical Devices Operator Ordinance. In this case you as the user are legally obligated to execute safety controls as described in Chapter 6.1.

# 2 Operating concept

#### 2.1 Control panel



#### 2.1.1 Ergonomic control panel

The control panel possesses a display, the main switch, the plug for the connector of the patient cable and the intensity regulator. These elements are easy to recognize and to operate and their functions are described in detail in the following chapters 2.1.2 to 2.1.3

#### 2.1.2 Display

The device is equipped with a **Graphic display** . There, clear notes are provided to start the therapy; the parameters of the selected type of current are indicated.

#### 2.1.3 Intensity regulator/Modification regulator

With the Intensity regulator you can switch through the menu of the program. Push on the button of the regulator if you want to choose the function indicated on the display.

During the therapy you can set the output voltage with the Intensity regulator. It is furnished in the form of a rotor pulse generator. The current increases by turning right (in + direction) and is reduced by turning left (in - direction). The numerical value is shown on the display in mA. To find the wanted intensity you may possibly turn the regulator clockwise for more than one rotation.

The Intensity regulator is also used as modification regulator for the basic settings. (chapter 3.4).

#### 2.2 Short instructions

Apply the electrodes to both thights like shown on these two pictures.





White connector

Black connector

Figure 2: Electrode placement

First, wet the black side of the conductive rubber electrodes with contact spray. Push the spray button for one or two times and disperse the fluid on the black side with your fingers.

Apply one electrode (80 x 120) each to the thigh just above the knee and fix each electrode with a velcro band.

Apply one electrode (80 x 120) each to the thigh just below the groin and fix each electrode with a velcro band.

The electrodes above the knee must be connected with the black connectors of the patient cable.

The electrodes below the groin must be connected with the white connectors of the patient cable.

Start the unit with the main switch on the front of the device. "Adjust the intensity until you get a muscle contraction" appears on the display.

Increase the intensity until you can see a <u>visible muscle contraction</u> on the thigh (Maybe some rotations clockwise, 5 is a normal value) A typical value for the current is about 160 mA. However intensities from 80 up to more than 250 mA are common practice. The chosen intensity should be comfortable for the patient.

The therapy is now started.

During therapy the intensity may decrease about 10 - 20 mA. If required, the intensity can be changed.. It is recommendable to do the adjustment in the active phase (during the contraction).

At the end of the therapy, the current to the patient will be automatically reduced to zero. If you want interrupt or stop the therapy, you can decrease the intensity to 0 by turning the Intensity regulator counterclockwise. After use the electrodes can be cleaned with a wet cloth.

HiToP® 191 9



Figure 3: therapy with the HiToP® 191

# 3 Start of operation

#### 3.1 Transport and installation

The device for High Tone Therapy is a portable unit. The unit may be placed on any plane horizontal surface. The distance between device and wall must be at least 20 cm.

The device for High Tone Therapy corresponds to the regulations DIN/VDE 0750, EN 60601. It is a device of safety class II. Within the scope of the Medical Device Directive the device for High Tone Therapy belongs to class IIa (see also Chapter 3.5 and safety precautions).



### Warning!

Note for use in clinical practice:

The unit is not designed to be used at non-explosion-proof places. If it is used in dangerous areas of anesthesia departments, the possibility of an explosion cannot be excluded.

If the patient and/or the patient cable is directly exposed to a radiator of a medical device for high frequency heat therapy, a damage of the device or a threat to the patient cannot be excluded. As a rule, a safety clearance of 2 to 3 m is enough.

#### 3.2 Connection and switch-on

The device for High Tone Power Therapy was set to be connected to a supply voltage of 100 V up to 240 V and will be switched automatically to the right supply voltage by the unit. Irrespective of the supply voltage, the device is appropriate for power frequencies of 48 to 62 Hz.

Connect the device for High Tone Therapy with the mains cable to a shockproof socket. The device is switched on by the main switch at the front of the device. This inhibits erroneous, unintended disconnection of the device during normal operation.

On the top of the device you find an integrated box for the accessory. When you open the cover, you can put the accessories (electrodes, velcro band and patient cable) in this box.



Figure 4: device with opened accessory box

### 3.3 Preparing the electrodes

The 4 white velcro bands must be thread in the electrodes as shown on this picture:

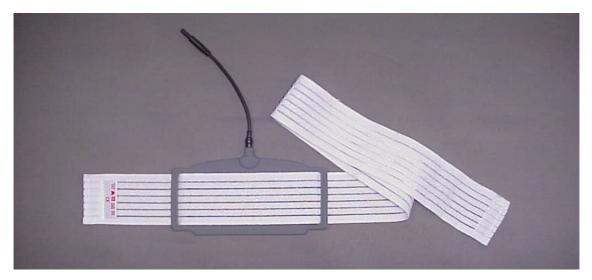


Figure 5: velcro bands with threaded electrodes

The side of the velcro band, where the washing instructions are seen, must face upwards and be placed 5-10 cm over the edge of the electrodes. The velcro fastener has to face upwards on this side.

#### 3.4 Basic settings

In the basic setting you can do modifications which will be stored in the non-volatile memory.

Do the following steps to modify the parameters of HiToP® 191.

Switch off the unit.

Switch on the unit while pressing the Intensity regulator.

On the display you will see the selectable settings.

#### Menu

Language
Treatment time
Service menu

Exit menu

You can select between the settings with the Intensity regulator.

After selection confirm your choice by pressing the button of the Intensity regulator and you can modify the values.

When you have taken your choice you can switch off the unit. Your modifications will be stored in the nonvolatile memory.

If you want to start the therapy immediately afterwards you can select the "Exit menu" to get into the therapy mode.

#### 3.4.1 Treatment time

The treatment time can be set in steps of 5 minutes between 30 and 60 minutes.

# Treatment time

55 min.

With the Intensity regulator you can modify the treatment time to the requested value. By pressing the Intensity regulator you store the value to the non-volatile memory.

#### 3.4.2 Language

In the language setting you can select between german, english, spanish, italian, czech, portuguese, russian and polish language.

# **Language**

deutsch česky english português español русский italiano polski

With the Intensity regulator you can choose the language. By pressing the Intensity regulator you store the value to the non-volatile memory.

#### 3.4.3 Service menu

The service menu is only used by service agents.

#### 3.4.4 Exit menu

With the Exit menu setting you can choose the therapy mode by pressing the button of the Intensity regulator and start the therapy program by adjusting the intensity (see chapter 4.2 treatment details).

#### 3.5 Important notes and safety precautions



### Warning!

It is imperative to comply with the notes and safety precautions in this user manual. The unit should only be used for the treatment described in this user manual.

- In case of patients with an implanted electronic device please carry out high tone therapy only after having checked whether there is any risk.
- Turn off cell phones, or place them at a distance of 2 3 m from the device.
- Cardiac pacemakers can extremely be disturbed. In these cases, the therapy should be only carried out under continuous pulse and ECG control. Take regards to the right electrode placement on the thighs. In this case, the treatment may be performed without control.
- If the patient and/or the patient cable is in direct range of high-frequency, short-wave or micro-wave therapeutic devices, a damage to the device or an injury of the patient cannot be excluded. Please keep a distance of at least 2 to 3 meters.
- A simultaneous connection of the patient to a high-frequency surgery device can lead to burns under the electrical stimulus electrodes.
- The device is not meant for use in non-explosion-proof places. If it is used in dangerous anethesia areas, an explosion is possible.
- Do not use the unit while taking a bath.
- Apply the electrodes only to those parts of the body which are described in the user manual.
- Do not connect other persons with the electrodes.
- Keep the unit away from children.

In case of all recognizable failures immediately contact gbo Medizintechnik AG, or one of the service agencies authorized by gbo Medizintechnik AG.

# 4 Therapy

### 4.1 General notes about the therapy

For the therapy we use a muscle stimulation. The muscle stimulation is generated with  $HiToP^{\otimes}$  frequencies. The current is applied by rubber electrodes which are moistured with contact spray. During the treatment the muscle is contracted in intervals. An interval consists of a 3 seconds rise time (intensity increases), a 3 seconds hold time (intensity is constant on the maximum setted before) and a 3 seconds break time (Intensity = 0).



#### Note!

If you like to interrupt or stop the treatment, decrease the intensity to zero by turning the Intensity regulator counterclockwise.

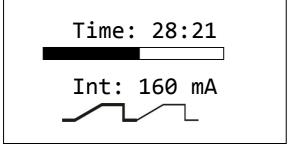
#### 4.2 Treatment details

- 1. Switch on the unit
- 2. You see the start display:
- 3. On the display the following message appears:

#### HiToP 191

Adjust the intensity until you get a muscle contraction.

- 4. Increase the intensity clockwise by turning the Intensity regulator until you see a visible muscle movement.
- 5. On the display the following message appears:



This shown display is only for example! Figures may differ in your therapy!

6. The therapy starts. The therapy timer is shown on the display and decreases in steps of seconds. Above the timer the intensity of the released voltage is shown on the display.

- 7. By pressing the Intensity regulator you can select between the overview display and the detailed view (as shown in chapter 4.3 Display in Detail).
- 8. In the detailed view you see some additional informations:

Time: 59:22

U: 12.1 V R:75V/A

I: 160 mA P: 2062 mW This shown display is only for example! Figures may differ in your therapy!

9. The treatment stops after the treatment timer reaches zero. You can also stop or interrupt the treatment by decreasing the intensity to zero.

#### 4.3 Display details

#### In the detailed view, the following values are shown:

Display data	Meaning	
TIME:	remaining time of the actual therapy	
U:	released voltage	
R:	patient's resistance	
I:	released current	
P:	released power	
<b>/</b> /	swelling active/inactive	

Table 1: Information in the detailed view

#### Some information on the detailed view:

In the detailed view you can recall treatment values like shown in the table above. The time shown is the treatment time and it is decreased in steps of seconds. When the treatment timer reaches zero, the unit stops the treatment and the intensity is set to zero.

The values for voltage (U) and current (I) can be used as an indicator for the following therapies. We are not able to give information about the absolute values of voltage and current because each patient reacts differently sensible to the current.

A common value for muscle contraction is between 150 - 200 mA. This setting should result in a contraction of both thights, visible and noticable by the patient.

The patient's resistance (R) gives information about the electric conductivity of the system. The resistance should fit to the area of 30 - 200 Ohms. The reason for a resistance greater than 200 Ohms may be:

- No contact spray was used to moisten the electrodes
- Bad contact because of oil and/or creme on the skin
- No contact of the distribution cable to one of the electrodes

The released power (P) is the product of voltage and current and gives some information about the released energy for one treatment.

#### 4.4 Duration and frequency of treatment

The duration of treatment is pre-set to 60 minutes. In the basic settings (see chapter 3.4.1 Treatment time) the treatment time can be set from 30 to 60 minutes.

The frequency of the treatments depends on the intensity of the polyneuropathic pain. In the beginning of the therapy (first 2-4 weeks) the treatment should be done daily. Later on the treatment interval of 3 days was very effective for many patients.

For the treatment of your polyneuropathic pain you should find your personal treatment interval.

Please treat your polyneuropathic pain every day to prove the HiToP® therapy. If you experience less pain or no pain, you can increase the interval of treatment. Evaluate when the pain between the treatment comes back and increase the treatment interval. With this method you can evaluate your personal optimum treatment interval.

### 5 Electrodes

The standard accessories for HiToP® 191 include rubber electrodes of 120 x 80 mm.

#### 5.1 Electrode application

The therapy shall always be carried out in a comfortable and relaxed position. The joints shall be placed in an angular position, so that they are placed in a relaxed position, from which both the flexor as well as the extensor muscles can be stimulated.

In general, the preparation and application of the electrodes is carried out as follows:

- 1. Connect the electrodes to the patient cable.
- 2. Connect the patient cable connector to the output plug on the frontside of the device.
- 3. Wet the conductive rubber electrodes with contact spray to avoid current sensations on the skin. Push the spray button for one or two times and disperse the fluid on the black side of the electrodes with your fingers
- 4. Remove oil and creme of the skin with a cleaning tissue.
- 5. Apply the electrodes as shown on page 8.
- 6. Apply the Velcro strap in a way that the electrode fits completely.



# Warning!

- Do not apply the electrodes on skin injuries. Even minor abrasions can cause a burning. Also, you may not be able to judge the current intensity objectively. If this cannot be avoided, apply zinc ointment or vaseline to cover the affected parts of the skin.
- The electrodes must adhere completely to the skin in order to avoid excessive local current density. Otherwise there can occur erythemas, and sometimes even burns.

# 6 Maintenance

Efficiency, reliability and safety characteristics of the device for High Tone Therapy are only guaranteed in case of proper use in accordance with the operating instructions. Safety control, maintenance work, repair work and modifications shall be carried out only by the manufacturer or the service agents authorized by him. In case of a failure, parts which influence the safety of the device shall be only replaced by original spare parts of the manufacturer. The electric installation shall be carried out in accordance with the requirements of VDE/IEC. The device does not contain any parts which need maintenance work done by the user.

### 6.1 Safety controls

Commercial users are obligated to keep the Medical Device Directive and documentation of the safety controls. The safety controls have to be carried out on the basis of this directive. Here, the operator regulation has to be especially observed.

Irrespective of the legal rules or beyond the scope of the Medical Device Directive, it is recommended to have the device checked at 12-months intervals by the manufacturer or by an authorized service agency.

The check shall consist of at least the following:

- Electrical safety check in accordance with the check plan of the manufacturer;
- Check of the device in regard to external integrity;
- Check of all display and operating elements in regard to damage;
- Check of all inscriptions in regard to legibility
- Check of all functions according to the user manual.



#### Note!

- Private users do not obligate to the duties mentioned above.
- The Medical Devices Operator Ordinance is not valid for countries outside EU.

#### 6.2 Cleaning, disinfection and care

#### 6.2.1 Cleaning the device

For cleaning the device for High Tone Therapy and its accessories, do use only a soft, fluffless cleaning tissue or common cleaner for plastic material. Do not use any abrasive cleaner.



#### Warning!

Do not clean the device under running water and do not use even liquid abrasive cleaner!

Prior to cleaning or disinfection unplug the mains plug out of the socket!

The device is suited for wiping disinfection. No liquids should penetrate the device. Plugs or sockets must never get wet. For cleaning or disinfection, the device may not be sprayed on.

#### **6.2.2 Cleaning Electrodes**

You can clean the electrodes after a treatment by using some warm water. Wash off the rest of the contact spray. Dry the electrodes with a cleaning tissue or let them air-dry.

**Note!:** The conductivity of the electrodes is optimized by using a big part of graphite. Therefore, while using and also while cleaning the electrodes black color may come off.

# 7 Explanation of the used signs



CE Conformity sign.



Caution!

Observe the instructions for use!



Application part ungrounded, safety degree type BF.



This product complies with WEEE Directive 2002/96/EG (waste electrical and electronic equipment). Separate collection for electrical and electronic equipment.

# 8 Technical data

Mains voltage and frequency:	100 V – 240 V, 48 - 62 Hz			
Current consumption:	With 115 V: max. 1080 mA With 230 V: max. 540 mA			
Output current:	max. 280 mA			
Output voltage:	max. 50 V eff.			
Admissible loaded impedance:	30 Ω5 kΩ			
MDD device class:	IIa			
Safety class:	II in accordance with IEC 601			
Safety degree:	BF in accordance with IEC 601			
Protection against ingress of water:	IP X1			
Dimensions:	13,5 cm x 23 cm x 23 cm (H x D x W) Height at opened case: 17,5 cm			
Weight:	1.4 kg (without accessories)			
Color:	white RAL 9002			
Display:	LCD backlighted, 128 x 64 dots full graphic			
Surrounding conditions:	Operation of the device:	Temperature range +15 °C +40 °C Relative air humidity 30 75 %		
	Transport and storage:	Temperature range -10 °C +50 °C Relative air humidity < 90 %, none condensing		
Types of current:	s of current: Sinusoidal currents of 4096 - 32768 Hz			

gbo Medizintechnik AG reserves the right to modify design and specification without prior notice.

#### 9 Accessories

Article		Article number
HiToP® 191 Extend of supply	<ul> <li>Connection cable 191</li> <li>Easy-Fix-electrode 80 x 120</li> <li>Velcro straps</li> <li>Contact spray</li> <li>User's manual HiToP® 191 in english</li> <li>Short form instruction 191 in english</li> </ul>	017-0-0191

Following accessories can be ordered additional or for replacement:

Article	Article number
Distribution cable 191	017-0-0067
Easy-Fix-electrode 80 x 120 mm (with fixation slot) (package of 2)	017-0-0062
	017 0 0070
Easy-Fix-electrode 80 x 120 mm (with fixation slot) (package of 4)	017-0-0070
Velcro straps 80 cm x 5 cm (4 pc.), white (for Easy-Fix-elektrodes)	017-0-0059
Contact spray	017-0-0068
User's manual HiToP <sup>®</sup> 191 in english	017-7-0138
Short form instruction HiToP® 191 in english	017-7-0139



# Note!

Use gbo original accessories only to guarantee the safe function of the unit.

# 10 Error messages

#### 10.1 Error messages on the display

#### **Error 1: current limit:**

This error message appears, when a short circuit of the electrodes causes a current which exceeds the maximum valid value.

#### **Error 3: current monitoring:**

This error message appears, when contact problems in the cable system causes a strong fluctuation of the current.

#### Error 4: open circuit:

This error message appears, when there is no current flow. This can be caused by a cable defect or an error in the electrode placement.

#### **Error 5: Unduly high temperature:**

This error message appears, when the temperature of the unit increases unduly high. Please switch off the device and let it cool down. Don't switch on the device until you are sure it has cooled enough down. If the error message appears frequently please contact your service agents or the manufacturer.

#### 10.2 Further errors

symptom	cause and action
Device can not be switched on, no display shown.	Please check the main plugs and sockets. Contact if necessary your service agents or the manufacturer.

Please contact your service agent or the manufacturer if the problems cannot be solved by the measures mentioned above.

Please note that the unit may be placed on plane horizontal surface. The device must not be placed in front of radiators and should not be covered with pillows or blankets during the therapy. Also the ventilation slots on the bottom of the unit should not be covered.

# 11 Appendix

# Notes in accordance with the EC Directive and Medical Device Directive

The HiToP® 191 is a line-powered device for High Tone Power Therapy of safety class II.

The device is in accordance with the EC directive for Medical devices (93/42/EWG) and therefore carries the CE sign with the Notified Body's number. The corresponding graphical symbol is placed on the type plate.

According to the Medical Device Directive, **HiToP**® **191** is a device of class **IIa**.

The manufacturer is only responsible for the safety, operational reliability and functionality of the device if:

- the device is used in accordance with the instructions for use;
- the electrical installation of the location where the device will be used corresponds to the respective current requirements of electrical safety;
- the device is not used in hazardous environments and humid locations;
- the mounting, amplifications, readjustments, modifications or repair works are carried out only by personnel authorized by the manufacturer;
- the operator regulation of this EC directive is observed within the scope of the Medical Device Directive.

You may obtain technical support by the manufacturer, dealers or services authorized by the manufacturer. The product's life scheduled by the manufacturer is 10 years.

The **HiToP**<sup>®</sup> **191** is an electronic device. For its disposal the respective regulations for electronic devices must be observed. Incidentals have to be disposed with residual waste.

On request, the manufacturer will provide further technical descriptions for all repairable parts of the device, such as circuit diagrams, spare parts lists, and adjustment instructions as far as these are of use for the qualified technical staff of the operator.

#### **Comments on electromagnetic compatibility (EMC)**

Medical, electrical devices are subject to special precautions concerning the EMC. They must be installed and operated according to the EMC-advice given in the accompanying documents. In particular medical, electrical devices may be influenced by portable and mobile RF-communication devices.

The manufacturer guarantees the conformity of the unit with the EMC-requirements only when accessories which are listed in the EC declaration of conformity are used. The use of other accessories may cause an increased emission of electromagnetic disturbances or may lead to a reduced electromagnetic immunity.

The unit must not be placed physically close to other devices or stacked on them. If such an order is necessary nevertheless, the unit must be observed in order to check it for the intentional operation.

You find more EMC comments in the Chapter "Warnings and Safety Precautions" of this manual as well as in the Technical Information on the next two pages.

In accordance with the EMC regulations for medical products we are obliged by law to provide the following information.

#### Guidance and manufacturer's declaration — electromagnetic emissions

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions, CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public
Harmonic emissions, IEC 61000-3-2 (*)	Class A	low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuation/flicker emissions, IEC 61000-3-3 (*)	Complies	

(\*) Note: For devices with a power consumption between 75 W and 1000 W only.

#### Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Immunity test	IEC 60601- test level	Compliance level	<b>Electromagnetic environment –</b>	
-		_	guidance	
Electrostatic discharge (ESD), IEC61000-4-2	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with	
	±8 kV air	±8 kV air	synthetic material, the relative humidity should be at least 30 %.	
Electrical fast transient/burst, IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.	
	±1 kV for input/output lines	±1 kV for input/output lines		
Surge, IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital	
	±2 kV common mode	±2 kV common mode	environment.	
Voltage dips, short	$<5\%$ $U_{\tau}$	<5% U <sub>τ</sub>	Mains power quality should be that of a	
interruptions and voltage variations on power supply input lines,	for ½ cycle (>95% dip)	for ½ cycle (>95% dip)	typical commercial or hospital environment.	
IEC 61000-4-11	40% U <sub>τ</sub>	40% U <sub>τ</sub>	If the user of the equipment requires	
	for 5 cycles	for 5 cycles	continued operation during power mains	
	60% dip)	60% dip)	interruptions, it is recommended that the equipment be powered by an	
	$70\%~\mathrm{U_{\tau}}$	$70\%~\mathrm{U_{\tau}}$	uninterruptible power supply or a	
	for 25 cycles	for 25 cycles	battery.	
	30% dip)	30% dip)		
	<95% U <sub>T</sub>	<95% U <sub>τ</sub>		
	for 5 s	for 5 s		
	(>5% dip)	(>5% dip)		
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or	
Note: $U_{\tau}$ is the a.c. mains voltage prior to application of the test level.				

#### Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment

user of the equipment should assure that it is used in such an environment.					
IEC 60601- test level	Compliance level	Electromagnetic environment –			
	_	guidance			
		Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
		Recommended separation distance:			
3 V <sub>rms</sub> 150 kHz to 80 MHz	3 V <sub>eff</sub>	d=1.2√P			
3 V/m 80 MHz to 2,5 GHz	3V/m	d=1.2\forall P for 80 MHz to 800 MHz d=2.3\forall P for 800 MHz to 2.5 GHz			
		Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m).			
		Interference may occur in the vicinity of equipment marked with the following symbol:  (((2)))			
	3 V <sub>rms</sub> 150 kHz to 80 MHz 3 V/m	$\begin{array}{ c c c c c c }\hline \textbf{IEC 60601- test level} & \textbf{Compliance level}\\ \hline & & & & & \\ \hline & & & & & \\ \hline & & & & $			

# Recommended separation distances to portable and mobile RF communication equipment

The equipment is intended to be operated in an electromagnetic environment, where radiated RF interference is controlled. The user can help in avoiding interferences by means of meeting minimum separation distances between portable and mobile RF communication equipment (transmitters) according to the maximum output power of the communication equipment.

Rated power of the	ver of the Separation distance according to the tranmission frequency (m)			
transmitter (W)	150 kHz to 80 MHz d=1.2√P	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.5 GHz d=2.3√P	
0,01	0.12	0.12	0.23	
0,1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

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